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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,379	08/15/2001	Christian Kropf	2006-219/H03763	8884
55495	7590	08/31/2010		
PAUL & PAUL 2000 MARKET STREET Suite 2900 PHILADELPHIA, PA 19103-3229			EXAMINER ROBERTS, LEZAH	
			ART UNIT 1612	PAPER NUMBER
			MAIL DATE 08/31/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/868,379	<b>Applicant(s)</b> KROPP ET AL.
	<b>Examiner</b> LEZAH W. ROBERTS	<b>Art Unit</b> 1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### Status

1) Responsive to communication(s) filed on 19 November 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 8,9,13-16 and 20-25 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 8,9,13-16 and 20-25 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SCE/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date: _____	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

Applicants' arguments, filed in the Request for Continued Examination on November 19, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 103 - Obviousness (Previous Rejection)**

Claims 8, 9, 13-16 and 20-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rudin et al. (US 6,919,070) in view of Bagchi et al. (US 5,560,932). The rejection is maintained.

#### **Applicant's Arguments**

Applicant argues the hydroxyapatite disclosed by Rudin et al. is pure hydroxyapatite crystals whereas the components of the instant invention have a water-soluble protective coating. The surface modifiers disclosed by Bagchi et al. adhere to the hydroxyapatite but do not chemically bond to the hydroxyapatite. Applicant further asserts that the compositions of Bagchi et al. are made by reacting the reactants with decreasing pH and not increasing pH as recited by Applicant. Increasing pH results in

Art Unit: 1612

the colloid forming intermolecular crosslinkages with the particles. Applicant makes reference to the Declaration of Christian Kropf and argues that the particles of the instant claims comprise the inorganic nanoparticles attached to the skeleton of the gelatin, i.e. the colloid, to form a single entity that is linked together.

Applicant further argues that the product of the instant invention comprise particles that take on the structure of the colloid because they are attached to the colloid, whereas the compositions of the combined references comprise particles that are coated with no chemical bonding to the colloid. Applicant further asserts that there is no need to indicate in the claims the type of crosslink because support is provided that show the differences between the art and the instant claims and the product of the instant claims is obtained by a different process. These are not persuasive.

*Examiner's Response*

Although the hydroxyapatite of Rudin are pure hydroxyapatite, the teachings of Bagchi et al. would motivate one of ordinary skill in the art to coat the hydroxyapatite to inhibit aggregation due to inter-particle attractive forces. The claims recite the hydroxyapatite is modified, it does not, however, recite this modification is due to chemical bonding. Thus coating the hydroxyapatite would modify its structure.

Further the types of cross-links formed are not recited in the instant claims. The claims recite the colloids are absorbed onto the particles and make no mention of cross-links or that the colloid is interdispersed within the particle. Although the claims have

been amended to recite "and modifying said particle", the term modifying also encompass coating the surface because this would also modify the particle. Although Bagchi discloses that the drug does not chemically react with the modifier, some type of bonding must occur in order for the modifying agent to remain in contact with the drugs, especially in the case of a salt. As previously asserted in the previous office action in regard to the method of making the colloidal system, the instant disclosure teaches several ways to make the colloidal systems of the instant claims (see page 7 of the instant specification). It appears not all of the methods of making the product of the instant claims required an initial acidic solution in order to make the compositions of the instant claims. Further, the product of the instant claims and the product of the combined reference have the same function as being used in an oral composition and restoring dental enamel. The prior art product appears to differ from the claim product only in the method of obtaining the product. The burden of persuasion is on Applicant to show that the claimed product exhibits unexpected properties compared with that of the prior art. See MPEP 2144.04. The burden of persuasion has not been met by Applicant because Applicant has not shown that the methods of the combined teachings of Rudin and Bagchi do not yield particles that have some chemical linkages or that using the methods of Bagchi do not yield particles encompassed by the instant specification. Applicant bases their conclusion that chemical linkages do not occur based on the disclosure of Bagchi. It is reiterated that the burden is higher for applicant due to the "peculiar nature" of product by process claims, as discussed therein. The Declaration of Christian Kropf will be discussed below.

*Declarations by Christian Kropf*

Declarant asserts that US Patent Application 11/864,252 includes a TEM micrograph of a composition according to the invention, comprising hydroxylapatite and Type A gelatin. A copy of the TEM is enclosed as Exhibit 1. The gelatin is added to an alkaline calcium salt and alkaline phosphate salt or the alkaline calcium salt and alkaline phosphate salt may be added to the gelatin. The particles are attached to the basic skeleton of the gelatin and the placement depends on the protein component (colloid) used. Thus Applicant's particles are bonded to the colloid by chemical links and the Bagchi et al particles are free of chemical links. Further, Applicant's particles form one structure whereas Bagchi et al. particles do not.

*Response to the Declarations by Christian Kropf*

In regard to the TEM, the image is unclear, and it cannot be independently determined what information is disclosed by the image. Although the colloids of Bagchi et al. are disclosed as not being chemically attached to the particles they do coat the particles forming one structure. Further coating the particle does modify their surface because the coating is absorbed onto the surface, which is encompassed by the instant claims. Applicant does not appear to have performed a side by side comparison of the different methods of making the coated particles and has not effectively shown support that the particles differ from that of the combined references because the TEM provided

Art Unit: 1612

as support is not clear. Thus Applicant's assertion that hydroxyapatite forms bonds with the backbone of the gelatin used to make the particles encompassed by the instant claims does not appear to be supported and thus an independent evaluation of the data cannot be made.

For arguendo, even if the Declaration did distinguish the method of making the hydroxyapatite wherein the colloids were absorbed on the surface from methods disclosed by the art, the claims are not commensurate in scope with the showing. The showing discloses gelatine A as the colloid and the claims recite "gelatin, casein, starch, plant gums, cellulose ethers, methylcellulose, hydroxyethyl cellulose, carboxymethyl cellulose, hydroxyethylstarch and hydroxypropylguar". Thus, a showing using a specific gelatine is not representative of the various colloids recited in the instant claims because it cannot be concluded that all the polymers recited would react in the same manner.

Claims 8, 9, 13-16 and 20-25 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

Art Unit: 1612

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612